

REMARKS/ARGUMENTS

Claims 9-21 are active. Independent Claim 9 tracks and finds support in original Claim 1. Support for parts (1) and (2) of this claim is also found in the specification on page 7, lines 2-12. Part (3) finds support on page 17, section (6) of the specification and in Table 2 on page 18, which shows lower reactivity of the monoclonal antibody for blood plasma incubated at 37°C for 2 hours. Claim 10, directed to monoclonal antibody 55201, finds support in the specification on page 6, lines 13-19. Claims 12-14 find support on page 7, lines 20-26. Claims 15 and 16 find support on pages 6 and 7 of the specification. The hybridoma cell line 55201 is described on page 6, lines 14-15. The immunoassay of Claims 18-21 finds support in the disclosure on page 7, line 13-*et seq.* Accordingly, the Applicants do not believe that any new matter has been added. Favorable consideration is therefore respectfully requested.

The Applicants thank Examiner Nguyen for the courteous and helpful discussion of October 28, 2003. Claim language that would help address the indefiniteness rejections was discussed. Also, it was suggested that the Applicants narrow the claims to a specific monoclonal antibody (MAb 55201) to avoid the rejection under 35 U.S.C. 112. The Applicants have now revised the claim language as discussed, however, rather than limit the claim set to one specific monoclonal antibody; they now present experimental data showing that other monoclonal antibodies having the same characteristics as monoclonal antibody 55201 may be reproducibly obtained using the methodologies described by the specification for MAb 55201 without undue experimentation. The claim set has been revised in view of the Examiner's suggests and also in view of this experimental data. Favorable consideration is now respectfully requested.

Priority

The Applicants thank Examiner Nguyen for acknowledging the receipt of the foreign priority documents.

Rejection—35 U.S.C. §112, first paragraph

Claims 1-8 were rejected under 35 U.S.C. 112, first paragraph as lacking adequate enablement for monoclonal antibodies other than MAb 55201 produced by hybridoma cell line FERM BP-6938. The rejection of Claims 1-8 is moot in view of their cancellation.

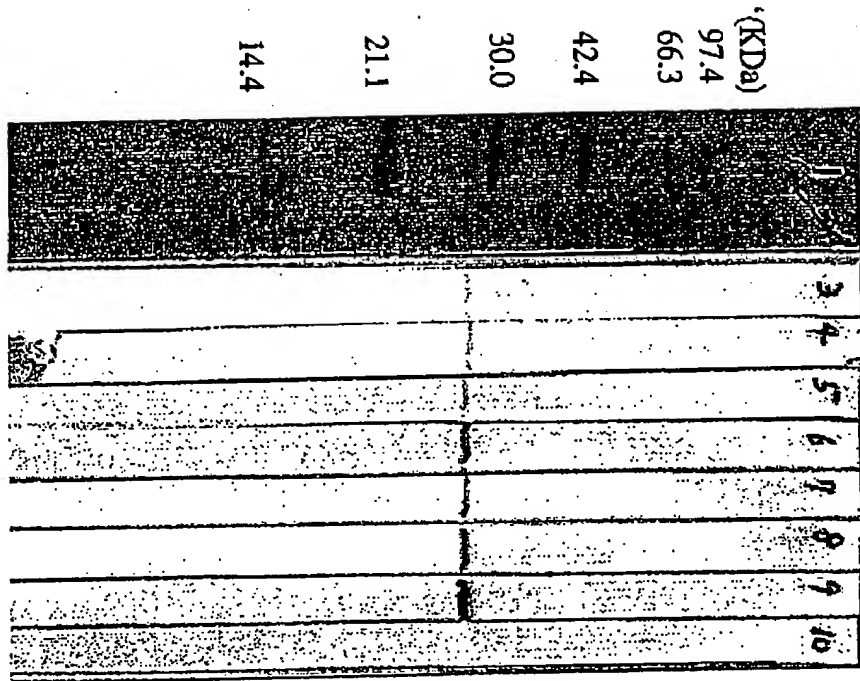
The Applicants respectfully submit that this rejection would not apply to the present claims in view of the experimental data presented below showing that other monoclonal antibodies having the same characteristics as MAb 55201 can be isolated using the same methodology as used to make MAb 55201. Briefly, at least two other monoclonal antibodies were produced and isolated using the same procedures used to make MAb 55201. These other antibodies are designed monoclonal antibody 55205 and monoclonal antibody 55207.

As shown in Supplemental Figure 1 monoclonal antibodies 55201, 55205 and 55207 each bind to a unique band corresponding to apoA-I as shown by Western Blotting.

As shown by Table A (see next page), monoclonal antibodies 55201, 55205 and 55207 bind to HDL containing apoA-I alone (GtXapoA), but did not react with HDL containing apoA-II (GtapoA-II).

Supplemental Figure 3, shows that monoclonal antibodies 55201, 55205 and 55207 all exhibit a similar pattern of reactivity with respect to apo-A fractions separated by gel-filtration.

Supplemental Fig. 1



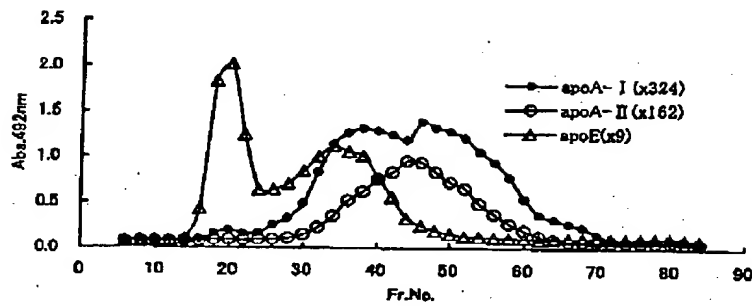
No.	Antibodies
5	55205
7	55207
9	14208
10	Normal Mouse IgG

Table A

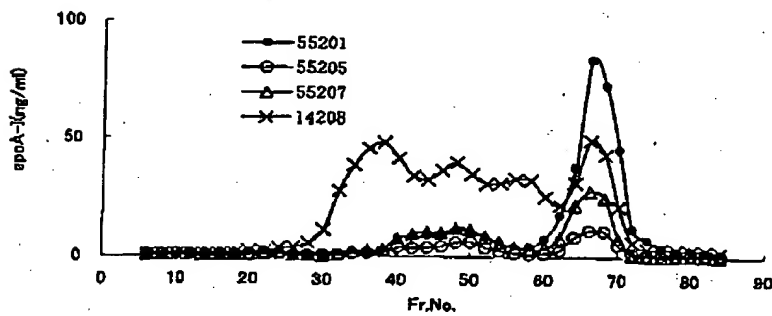
	Abs.492nm	
	GtXapoA	GtXapoA-II
55201	1.517	0.089
55205	1.716	0.083
55207	1.343	0.106
14208	1.302	1.308

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Supplemental Fig. 2



Supplemental Fig. 3



Accordingly, in view of these data, the Applicants respectfully submit that undue experimentation would not be required of one with skill in the art to obtain a monoclonal antibody with the functional characteristics claimed in Claim 9.

Rejection—35 U.S.C. §112, second paragraph

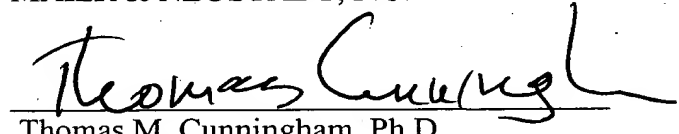
Claims 1-8 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. These rejections are moot in view of the cancellation of these claims.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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